K122136

510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R. Part 807.92.

Purpose of Submission: Vital Images, Inc. hereby submits this traditional 510(k) to provide notification submission for an addition to the Indications for Use of our already cleared VitreaView software.

Submitter:
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SEP 7 2012

Establishment Registration: 2134213

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510(k) Type: Traditional 510(k)

Summary Date: August 27,2012

Device Name

Trade Name: VitreaView
Common Name: Picture Archiving and Communications System
Classification Name: System, Image Processing, Radiological (21 C.F.R. 892.2050,LLZ)

Predicate Device: VitreaView (K111892)

Device Description:

VitreaView is a cross-browser, cross-platform, zero-footprint universal image viewer solution capable of displaying both DICOM and non-DICOM medical images. VitreaView enables clinicians and other medical professionals to access patients' medical images with integrations into a variety of medical record systems, such as Electronic Health Record (EHR), Electronic Medical Record (EMR), Health Information Exchange (HIE), Personal Health Record (PHR), and image exchange systems. It supports the physician in medical image viewing and treatment planning.

VitreaView offers medical professionals a universal viewer for accessing imaging data in context with reports from enterprise patient health information databases, fosters collaboration, and provides workflows and interfaces appropriate for referring physicians and clinicians. IT departments will not have to incur time to install client systems, due to the zero footprint, zero- download nature of VitreaView. VitreaView offers scalability to add new users as demand grows, may be deployed in a virtualized environment, and is designed to be integrated with enterprise patient health information databases. When accessed from a mobile tablet, no advanced image processing is performed by the tablet.

Some of the general features include:

- Performance speed
- Zero-footprint architecture
- DICOM and non-DICOM display
- Vendor neutrality
- Function within a virtual environment
- Multi-modality review of data

- Basic image review tools (zoom, pan, measure)
- Easy study navigation and search capability
- Radiology key images
- Comparative review
- Cross-platform viewing capabilities (Windows, Linux, Mac OS)
- Leveraging of next-generation protocols for image viewing (i.e. MINT)
- Single sign-on
- MPR and 3D viewing
- Access on various iOS and Android tablet devices through the default internet browser

Intended Use / Indications for Use:

VitreaView is a medical image viewing and information distribution application that provides access, through the Internet and within the enterprise, to multi-modality softcopy medical images, reports and other patient-related information, that may be hosted within disparate archives and repositories for review, communication and reporting of DICOM and non-DICOM data. VitreaView is not intended for primary diagnosis. When accessed from a mobile tablet, VitreaView is for informational purposes only and not intended for diagnostic use.

Display monitors used for reading medical images for diagnostic purposes must comply with applicable regulatory approvals and with quality control requirements for their use and maintenance.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 MP resolution and meets other technical specifications reviewed and accepted by FDA.

Summary of Non-Clinical Tests:

VitreaView was designed, developed, and tested according to written procedures. Testing included verification, validation, and evaluation of previously acquired medical images.

The following quality assurance measures were applied to the development of VitreaView:

- Risk analysis
- Requirements reviews
- Design reviews
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

The software verification team had a primary goal of assuring that the software fully satisfies all expected new and previously defined detailed level system requirements and features. This was accomplished through new feature test case authoring on the system requirements and their execution. In addition to reviewing and authoring test cases based upon the system requirements and features the verification team reviewed and monitored the Requirements Traceability Matrix (RTM) to ensure coverage of said items as well as review and authoring of additional cases to meet the FMEA submitted for the project.

The software validation team had a primary goal of assuring that the software conforms to user needs and intended uses. The result of the validation team's efforts was evidence that system requirements and features were implemented, reviewed and met through workflow testing.

The software validation team provided internal validation of the VitreaView product once verification was completed. Internal validation included internal beta testing, internal user acceptance testing, and installation and upgrade path testing.

The software was designed, developed and tested according to written procedures. Software testing was completed to ensure the new feature functions according to its requirements and interacts without impact to existing functionality.

Summary of Clinical Tests:

The subject of this traditional 510(k) notification, VitreaView, did not require clinical studies to support safety and effectiveness of the software.

Cyber and Information Security:

VitreaView is designed to follow security best practices, including those outlined by the Open Web Application Security Project (OWASP) and Health Insurance Portability and Accountability Act (HIPAA), to limit the risk of unauthorized access to the system or data. Security is enforced at multiple layers within the system.

Measurement Accuracy:

Measurements and orientation in VitreaView were verified using various imaging phantoms. These imaging phantoms contain markers at known positions, distances, and angles from one another. The known positions, distances, and angles were used as input into expected results for verification tests that verified the spatial accuracy of image rendering of 2D and 3D images, the accuracy of distance, angular measurement, and navigational tools, and the accuracy of orientation markers within the VitreaView application.

Performance Standard:

The software is designed to meet NEMA PS 3.1-3.20 (2011) *Digital Imaging and Communications* in Medicine (DICOM).

Conclusion:

The VitreaView software is substantially equivalent to the predicate device and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 7 2012

Mr. Ian Nemerov
Vice President, General Counsel & Secretary
Vital Images, Inc.
5850 Opus Parkway, Suite #300
MINNETONKA MN 55343

Re: K122136
Trade/Device Name: VitreaView
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 17, 2012
Received: July 18, 2012

Dear Mr. Nemerov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K122136

Device Name: VitreaView

Indications for Use:

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Prescription Use X _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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